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Europäisches
Patentamt

Generaldirektion 2

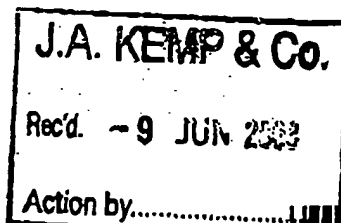
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Application No. 99 970 029.7-1257	Ref. N.82282 AMS	Date 06.06.2003
Applicant Sakai, Asahi		

Communication pursuant to Article 96(2) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(1) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 78(2) and 83(2) and (4) EPC.

One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (Rule 36(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Article 96(3) EPC).



VILLENEUVE J R J
Primary Examiner
for the Examining Division

Enclosure(s): 4 page/s reasons (Form 2906)

AA:
EIN:
RECC:
REGISTERED



Beachhold/Protokoll (Anlage)

Communication/Minutes (Annex)

Notification/Procès-verbal (Annexe)

Datum
Date
Date

05.06.2003

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Anmelde-Nr.:
Application No.:
Demande n°:

99 970 029.7

The examination is being carried out on the following application documents:

Text for the Contracting States:

AT BE CH LI CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE

Description, pages:

1-10 as originally filed

Claims, No.:

1-5 as originally filed

Drawings, sheets:

1/4-4/4 as originally filed

1. The following documents are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: US-4338190-A

D2: US-4618 343-A

2. The application does not meet the requirements of Article 84 EPC, because claim 1 is not clear, as no indication is given of the functional relationship between the filters.

2.1 Furthermore, the above-mentioned lack of clarity notwithstanding, the subject-matter of claim 1 as it stands does not involve an inventive step in the sense of Article 56 EPC, and therefore the requirements of Article 52(1) EPC are not met, the reasons being as follows:

2.3 Document D1 which is considered to represent the most relevant state of the art, discloses (the references in parentheses applying to this document; see D1, figures 1,



Bescheid/Protokoll (Anlage)

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Anmelde-Nr.:
Application No.: 99 970 029.7
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6): *An instrument for continuous recirculation of peritoneal dialysate to infuse and drain out the dialysate automatically through catheter(s) implanted in peritoneal cavity of human body, comprising (a) prefilter (9), (b) primary filter (604) comprising semipermeable membrane, (c) pump (present, but not referenced on figure 6, reference 405 on figure 4) for lowering the outside pressure of the primary filter (b) relative to the inside pressure. (d) secondary filter (609) comprising semipermeable membrane, (e) pump (8) for raising the pressure of supplemental liquor line relative to the inside of the secondary filter line.*

N.b. the filter (9) of figure 1 is also part of the embodiment of figure 6 (see D1, col 5, line 25)

2.4 The primary membrane of D2 is chosen to pass waste metabolites but to retain the proteins of the patient (see D2; col 4, lines 54-56) ; thus, the choice of a particular value of 30 000 Dalton as cutoff value for this membrane is not considered inventive. Also the choice of 5000 Dalton as cutoff value for a the secondary filter excluding bacteria from a solution of low molecular products is not regarded as involving an inventive activity (see for instance D2, claims 15-17)

2.5 The available prior art does not teach nor renders obvious a recirculation instrument as in claim 1 where the prefilter, the inside of the primary filter and the inside of the secondary filter are disposed in series on the recirculation line, as is the case in the application. This feature, in combination with the features of the present claim 1 would overcome the above objections concerning clarity and inventive step.

2.6 It is suggested therefore that a new independent claim be drafted to include these features, bearing in mind that the features known in combination in D1 should be placed in the preamble of such a claim in accordance with Rule 29(1) EPC.

3. Dependent claim 2 does not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC with respect to inventive step, the reasons being as follows:
Disposable, pre-assembled and sterile packaged fluid circuits are generally used in the field of peritoneal dialysis in association with durable control apparatus.

3.1 Claim 3 does not meet the requirements of Article 84 EPC in that the matter for



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which protection is sought is not clearly defined: It is not clear from the claim which elements are part of the instrument for which protection is sought. It is also not clear which parts can be connected together.

3.2 A possible way of clarifying claim 3 could be as follows (see description, page 6, lines 11-21):

The instrument for continuous recirculation of peritoneal dialysate according to Claim 1 or 2, comprising

- an instrument side part of an outflow joint for connection to a peritoneal side part of the outflow joint on a peritoneal catheter and
- an instrument side part of an inflow joint for connection to a peritoneal side part of the inflow joint on a peritoneal catheter;

these instrument side parts having a structure so as to be directly connectable to each other;

the instrument also comprising an isolated case in which the aforementioned joints may be fixed adjacent and so that the instrument side joint parts and the peritoneal side joint parts may be disconnected and connected by remote handling free from finger touch.

3.3 Dependent claim 2 and a new, clarified dependent claim 3 (for instance, as in paragraph 3.2 above) would be allowable with a revised independent claim as suggested in paragraph 2.5 above.

4. Claim 4 and 5 are not allowable because they refer to a surgical method for the treatment of the human or animal body, which is not regarded as having industrial applicability (Article 52(4) EPC).

5 If new claims are filed, attention should also be paid to the following:

5.1 The features of the claims should be provided with reference signs placed in parentheses to increase the intelligibility of the claims (Rule 29(7) EPC). This applies to both the preamble and characterising portion (see the Guidelines, C-III, 4.11).

5.2 To meet the requirements of Rule 27(1)(b) EPC, the document D1 should be identified in the description and the relevant background art disclosed therein should be briefly discussed.



Beschuld/Protokoll (Anlage)

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5.3 When filing amended claims the applicant should at the same time bring the description into conformity with the amended claims. Care should be taken during revision, especially of the introductory portion and any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).

5.4 In order to facilitate the examination of the conformity of the amended application with the requirements of Article 123(2) EPC, the applicant is requested to clearly identify the amendments carried out, irrespective of whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based. If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.



European Patent
Office

**SUPPLEMENTARY
EUROPEAN SEARCH REPORT**

Application Number
EP 99 97 0029

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	US 4 338 190 A (FROMMER MOSHE A ET AL) 6 July 1982 (1982-07-06) * column 4, line 43 - column 5, line 7; figures 1,6 *	1	A61M1/28
A	US 4 618 343 A (POLASCHEGG HANS-DIETRICH) 21 October 1986 (1986-10-21) * claims 21-23 *	1	
A	US 5 660 722 A (NEDERLOF BERND) 26 August 1997 (1997-08-26) * abstract; figure 1 *	1	
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61M
The supplementary search report has been based on the last set of claims valid and available at the start of the search.			
Place of search		Date of completion of the search	Examiner
THE HAGUE		14 November 2002	Villeneuve, J-M
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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